DURECT Corporation Announces Fourth Quarter and Full Year 2016 Financial Results and Update of Programs

Live Webcast of Earnings Call Today at 4:30 p.m. Eastern Time

CUPERTINO, Calif., March 14, 2017 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2016 and provided a corporate update.

- Total revenues were $3.5 million and net loss was $8.8 million for the three months ended December 31, 2016 as compared to total revenues of $5.2 million and net loss of $5.8 million for the three months ended December 31, 2015.
- Total revenues were $14.0 million and net loss was $34.5 million for the year ended December 31, 2016, compared to total revenues of $19.1 million and net loss of $22.7 million for the year ended December 31, 2015.
- At December 31, 2016, cash and investments were $25.2 million, compared to cash and investments of $29.3 million at December 31, 2015. Debt at December 31, 2016 was $19.9 million.

“For DUR-928, our novel epigenetic regulator which has potential for broad utility in metabolic disorders, acute organ injury and inflammatory conditions, we have completed six Phase 1 clinical trials to date, including dosing over 140 healthy volunteers and patients,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We are pleased with the excellent safety profile of DUR-928 in these trials as well as certain promising biomarker data seen in NASH patients. We look forward to presenting this data at the upcoming EASL meeting. We are also announcing today that we are investigating the use of DUR-928 as a topical agent for the potential treatment of psoriasis. In PERSIST, the POSIMIR pivotal Phase 3 clinical trial in post-operative pain, enrollment rates support completion of dosing in the third quarter of 2017 which would put us in position to obtain top-line results this year.”

Expected milestones in 2017:

- Reporting of DUR-928 Phase 1b and other data at scientific meetings, including the AASLD Emerging Trends Conference (March) and EASL (April)
- Commencing at least one Phase 2 trial with DUR-928, with primary sclerosing cholangitis (PSC) likely the first oral indication to be pursued
- Selecting lead topical formulations for DUR-928 that will be taken into a proof-of-concept clinical trial in psoriasis patients
- Completing enrollment in the Phase 3 POSIMIR clinical trial (PERSIST) in post-operative pain and announcing top-line results
- Potentially establishing a commercial partner for POSIMIR
- Reporting on top-line results from the Phase 3 trial with ORADUR®-Methylphenidate in Taiwan conducted by our partner Orient Pharma

Update on Selected Programs:

Epigenetic Regulator Program. DUR-928, our Epigenetic Regulator Program’s lead product candidate, is an endogenous, small molecule, new chemical entity (NCE), which may have broad applicability in several metabolic diseases such as nonalcoholic steatohepatitis (NASH) and other disorders of the liver, in acute organ injuries such as acute kidney injury, and in autoimmune/inflammatory disorders such as psoriasis.

Oral Formulation

- Our first patient trial utilizing DUR-928 was an open-label, single-ascending-dose safety and pharmacokinetic (PK) Phase 1b trial in liver function impaired (NASH) patients and matched control subjects. This study was conducted in Australia, evaluating single-dose levels (first a low dose and then a high dose) of orally administered DUR-928 in successive cohorts.

Twenty subjects with NASH and 12 matched control subjects received DUR-928.

- We observed a dose dependent reduction of certain biomarkers after a single oral dose of DUR-928. In both cohorts, IL-18, an inflammatory mediator implicated in both liver and kidney diseases, decreased hours after DUR-928 dosing, with the effect greater in the NASH patients. Full length CK-18 (a generalized cell death marker) and cleaved CK-18 (a cell apoptosis marker) were both greatly reduced after low and high doses of DUR-928, with the effect, again, more pronounced in NASH patients.
- An abstract for this study has been accepted and data from the study will be presented at the International Liver Congress™ 2017 organized by the European Association for the Study of the Liver (EASL) in Amsterdam, April 19-23, 2017.
- An abstract describing our two STAM™ NASH mouse model studies has been accepted at the AASLD Emerging Trends Conference 2017: Emerging Trends in Non-alcoholic Fatty Liver Disease in Washington, DC. That data will be presented on March 17, 2017.
- We will be participating in and presenting at 4:40 pm at the H.C. Wainwright NASH Investor Conference taking place on April 3, 2017 at the St. Regis Hotel in New York.
- We are actively working towards a Phase 2 trial in Primary Sclerosing Cholangitis (PSC), with an oral formulation of DUR-928. PSC is a chronic liver disease characterized by a progressive cause of cholestasis (decrease in bile flow) with inflammation and fibrosis of bile ducts. It is an orphan medical condition for which there is no established medical treatment.

Injectable Formulation

- Our second Phase 1b study with DUR-928, also being conducted in Australia, is an open-label, single-ascending-dose safety and pharmacokinetic study in patients with impaired kidney function (stage 3 and 4 chronic kidney disease) and matched control subjects.
- This study is being conducted in successive cohorts evaluating single-dose levels (first a low dose and then a high dose) of DUR-928 administered by intramuscular injection. The low dose cohort consisted of 6 kidney function impaired patients and 3 matched control subjects.
- Data from the low dose cohort showed the PK parameters between the kidney function impaired patients and the matched control subjects were comparable. After a PK/safety review of this cohort, patients are now being enrolled in the high dose cohort, utilizing a dose four times larger than the low dose cohort.
- We are working closely with expert advisors to design Phase 2 trials in one or more indications with an injectable formulation of DUR-928.

Topical Formulation

- We conducted an initial exploratory Phase 1b trial in psoriasis patients (n = 9 evaluable patients) in Australia. The decision to proceed with clinical testing in psoriasis was based on the anti-inflammatory and cell survival properties of DUR-928, including the downregulation of IL-17, full length CK-18, cleaved CK-18, as well as the results of a psoriasis study with DUR-928 in mice.
- The Phase 1b trial was conducted with intradermal micro injections of DUR-928, and we feel the results warrant further investigation. As a result, we have developed several topical formulations of DUR-928 that we are evaluating for a topical application microplaque trial which we expect to commence this year. We believe that there is a large unmet medical need for new topical drugs for psoriasis for use prior to systemic biologic treatments which often have significant associated side effects.

POSIMIR (SABER®-Bupivacaine) Post-Operative Pain Relief Depot. POSIMIR is our investigational post-operative pain relief depot that utilizes our patented SABER technology and is intended to deliver bupivacaine to provide up to 3 days of pain relief after surgery. We are in negotiations with a number of potential partners regarding licensing development and commercialization rights to POSIMIR, for which we hold worldwide rights.

- We expect to finish dosing patients in PERSIST, a POSIMIR Phase 3 clinical trial consisting of patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery, in the third quarter of 2017 and to have top-line results this year.
- In a previous clinical trial of 50 patients in the same surgical model (laparoscopic cholecystectomy), POSIMIR was compared with the active control bupivacaine HCl, against which POSIMIR demonstrated in a post hoc analysis an approximately 25% reduction in pain intensity on movement for the first 3 days after surgery (p=0.024) and for the first 2 days after surgery (p=0.0198), using the same statistical methodology specified for the current trial. There can be no assurance that the PERSIST trial will replicate these results.

REMOXY® ER (oxycodone) Extended-Release Capsules CII. Based on our ORADUR technology, the investigational drug REMOXY ER is a unique long-acting formulation of oxycodone designed to discourage common methods of tampering associated with opioid misuse and abuse.

- In September 2016, Pain Therapeutics (our licensee) received a Complete Response Letter from the FDA for REMOXY ER. Based on its review, the FDA has determined that the NDA cannot be approved in its present form and specifies additional actions and data that are needed for drug approval.
- We understand from its public disclosures that Pain Therapeutics had a meeting with the FDA in February 2017 to discuss the regulatory path forward for REMOXY ER, and that Pain Therapeutics will provide details of the FDA meeting after receipt of the final meeting minutes.

ORADUR-ADHD Program. ORADUR-Methylphenidate is an investigational drug that has the potential for rapid onset of action, long duration with once-a-day dosing, utilizes a small capsule size relative to the leading existing long-acting products on the market and incorporates our ORADUR anti-tampering technology. Orient Pharma, our licensee in defined Asian and South Pacific countries, has completed dosing a Phase 3 study in Taiwan and anticipates obtaining top-line results from that study in the second quarter of 2017. We retain rights to all other markets in the world, notably including the U.S., Europe and Japan.

Feasibility Projects and Other Activities. During the fourth quarter of 2016 and in 2017, we continued work on feasibility projects funded by large pharmaceutical companies as a means of demonstrating that our technologies can achieve the drug delivery objectives set forth by our collaborators and are worthy of further development.

Earnings Conference Call

A live audio webcast of a conference call to discuss fourth quarter 2016 results and provide a corporate update will be broadcast live over the internet at 4:30 p.m. Eastern Time on March 14 and is available by accessing DURECT's homepage at www.www.durect.com and clicking "Investor Relations." If you are unable to participate during the live webcast, the call will be archived on DURECT's website under Audio Archive in the "Investor Relations" section.

About DURECT Corporation

DURECT is a biopharmaceutical company actively developing new therapeutics based on its Epigenetic Regulator Program and proprietary drug delivery platforms. DUR?928, a new chemical entity in Phase 1 development, is the lead candidate in DURECT's Epigenetic Regulator Program. An endogenous, orally bioavailable small molecule, DUR-928 has been shown in preclinical studies to play an important regulatory role in lipid homeostasis, inflammation, and cell survival. Human applications may include acute organ injury, chronic metabolic disorders such as nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH) and other disorders of the liver both broad and orphan, and inflammatory conditions such as psoriasis. DURECT's advanced oral, injectable, and transdermal delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. One late-stage product candidate in this category is POSIMIR® (SABER®-Bupivacaine), an investigational analgesic product intended to address key unmet needs in postoperative pain management. Another late stage product candidate is REMOXY® ER (oxycodone), an investigational extended release pain relief drug based on DURECT's ORADUR® technology. For more information, please visit www.www.durect.com.

NOTE: POSIMIR®, SABER®, and ORADUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. POSIMIR, DUR-928, REMOXY ER and ORADUR-Methylphenidate are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding the potential benefits and uses of our drug candidates, including the potential use of DUR-928 to treat NASH, other disorders of the liver, kidney diseases or psoriasis or other inflammatory conditions, the potential use of POSIMIR to treat pain, the potential abuse deterrent properties of REMOXY ER and the potential use of ORADUR-ADHD to treat ADHD, clinical trial plans for DUR-928, POSIMIR and our other product candidates (including timing and potential results), potential reporting of Phase 3 results for ORADUR-methylphenidate, potential regulatory approvals of POSIMIR and REMOXY ER, potential markets for our product candidates, potential plans to license commercialization rights for POSIMIR and Pain Therapeutics' plans for REMOXY ER are forward-looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, the risks that future clinical trials of DUR-928 do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, that the PERSIST clinical trial of POSIMIR will take longer to conduct than anticipated or result in data that will not support a successful NDA

resubmission or product approval, that Pain Therapeutics may not be able to adequately address all of FDA's concerns regarding the REMOXY ER NDA or that there could be a delay in addressing such concerns, the potential that FDA may not grant regulatory approval of REMOXY ER, the risks of obtaining marketplace acceptance of REMOXY ER, if approved, the risk of delays in the commencement, enrollment or completion of other clinical trials, the risk that prior clinical trials (including prior trials of POSIMIR in laparoscopic cholecystectomy patients and Phase 1b trials of DUR-928) will not be confirmed in subsequent trials, the potential failure of clinical trials to meet their intended endpoints, the risk that Pain Therapeutics or Orient Pharma will discontinue development of REMOXY ER or ORADUR-Methylphenidate, respectively, or be delayed in development or regulatory submissions, the risk of adverse decisions by regulatory agencies or delays and additional costs due to requirements imposed by regulatory agencies, additional time and resources that may be required for development, testing and regulatory approval of DUR-928, potential adverse effects arising from the testing or use of our drug candidates, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations and risks related to our ability to obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q filed on November 1, 2016 under the heading "Risk Factors."

DURECT CORPORATION
CONDENSED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands, except per share amounts)
(Unaudited)

	Three months ended December 31		Twelve months ended December 31	
	2016	2015	2016	2015
Collaborative research and development and other revenue	$ 738	$ 2,264	$ 1,880	$ 7,832
Product revenue, net	2,779	2,903	12,145	11,292
Total revenues	3,517	5,167	14,025	19,124
Operating expenses:				
Cost of product revenues	955	993	5,290	3,905
Research and development	7,992	6,658	29,274	24,317
Selling, general and administrative	2,832	2,845	11,825	11,566
Total operating expenses	11,779	10,496	46,389	39,788
Loss from operations	(8,262)	(5,329)	(32,364)	(20,664)
Other income (expense):				
Interest and other income	31	43	143	237
Interest and other expense	(580)	(559)	(2,288)	(2,236)
Net other income (expense)	(549)	(516)	(2,145)	(1,999)
Net loss	$ (8,811)	$ (5,845)	$(34,509)	$(22,663)
Net loss per share				
Basic	$ (0.06)	$ (0.05)	$ (0.26)	$ (0.19)
Diluted	$ (0.06)	$ (0.05)	$ (0.26)	$ (0.19)
Weighted-average shares used in computing net loss per share				
Basic	139,636	120,911	133,163	118,523
Diluted	139,636	120,911	133,163	118,523
Total comprehensive loss	$ (8,819)	$ (5,925)	$(34,498)	$(22,764)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of December 31, 2016 (unaudited)	As of December 31, 2015[(1)]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,404	$ 3,583
Short-term investments	19,600	25,457
Accounts receivable	1,154	2,222
Inventories	3,782	3,917
Prepaid expenses and other current assets	2,486	3,142
Total current assets	32,426	38,321
Property and equipment, net	1,297	1,566
Goodwill	6,399	6,399
Long-term restricted Investments	150	250
Other long-term assets	236	236

Total assets	$	40,508	$	46,772
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	$	2,086	$	1,286
Accrued liabilities		5,060		4,970
Contract research liability		783		575
Deferred revenue, current portion		968		616
Term loan, current portion, net		19,853		–
Total current liabilities		28,750		7,447
Deferred revenue, noncurrent portion		1,879		2,269
Term loan, noncurrent portion, net		–		19,684
Other long-term liabilities		1,541		2,489
Stockholders' equity		8,338		14,883
Total liabilities and stockholders' equity	$	40,508	$	46,772

(1) Derived from audited financial statements.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/durect-corporation-announces-fourth-quarter-and-full-year-2016-financial-results-and-update-of-programs-300423515.html

SOURCE DURECT Corporation

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